REMARKS

Claim 1 is pending in the instant application. Claim 1 has been rejected. Claim 1 has been amended to replace the term "expressed" with the term --encoded--. Support for the term encoded is provided in the specification at pages 3 and 6. No new matter is added by this amendment. Reconsideration of the rejection of claim 1 is respectfully requested in light of the following remarks.

I. Rejection of Claim 1 under 35 U.S.C. § 102(a) and 102(e)

Claim 1 has been rejected under 35 U.S.C. § 102(a) and 102(e) as being anticipated by U.S. Patent 5,733,748. The Examiner suggests that U.S. Patent 5,733,748 teaches a method of utilizing Human Colon Specific Gene polypeptides as a diagnostic marker for colon cancer wherein "diagnosis is by detecting altered levels of CSG polypeptides in a biological sample, tissue, elevated levels of CSG polypeptides, wherein the assays are well known in the art, wherein the tissue can be biological fluids, cell samples diagnosing colon cancer comprising measuring levels of CSG polypeptides." The Examiner has acknowledged that the reference does not specifically teach a CSG protein encoded by SEQ ID NO:1. However, the Examiner suggests that absent

evidence to the contrary, the burden is on the applicant to prove that the claimed method of assaying CSG protein encoded by SEQ ID NO:1 is different from that taught by the prior art and to establish patentable differences.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants are providing herewith a copy of the amino acid sequence encoded by SEQ ID NO:1. Applicants have compared this sequence to polypeptides taught in U.S. Patent 5,733,748 and they are different. Thus, as evidenced by the sequence submitted herewith the CSG protein encoded by SEQ ID NO:1 is patentably different from the CSG proteins taught by U.S. Patent 5,733,748.

Withdrawal of this rejection under 35 U.S.C. § 102(a) or 102(e) is therefore respectfully requested.

II. Rejection of Claim 1 under 35 U.S.C. § 112, first paragraph

Claim 1 has been rejected under 35 U.S.C. § 112, first paragraph. The Examiner suggests that the predictability of protein translation is not necessarily contingent on mRNA expression due to a multitude of homeostatic factors affecting transcription and translation and that protein expression based upon mRNA expression can be unpredictable. In support of this

suggestion, the Examiner has cited a number of references relating to various proteins including ferritin polypeptide, ornithine decarboxylase, p-glycoprotein, and p53 protein. Further, the Examiner suggests that even if the protein were produced, information is not provided regarding how to differentiate between diagnosis of colon cancer and the diagnosis of herpes virus 1 or herpes virus 3, both of which the Examiner suggests share epitopes identical to the protein encoded by SEQ ID NO:1.

Applicants respectfully traverse this rejection.

With respect to the Examiner's suggestion of overlapping epitopes and an inability to differentiate between colon cancer and herpes virus 1 or 3, Applicants disagree that the potential 3 to 4 amino acid regions of overlap shown in the alignments provided by the Examiner would result in similar epitopes between herpesvirus proteins and the CSG of the present invention. In addition, the symptoms of a herpesvirus infection are quite different from symptoms of colon cancer. Thus, clearly even if there were some overlap in detection of the two, the skilled clinician could still differentiate diagnostically in a patient based upon other factors.

Further, as discussed in Section I, *supra*, Applicants have provided herewith the encoded amino acid sequence of SEQ ID NO:1. Applicants have compared this sequence to that of herpes virus 1 and 3 and do not see any overlapping amino acid regions nor shared epitopes of the encoded amino acid sequence of SEQ ID NO:1 and herpes virus 1 and 3. Accordingly, the Examiner's concerns with respect to detecting viral infection as opposed to colon cancer are particularly irrelevant with respect to the instant encoded amino acid sequence.

Further, Applicants respectfully disagree with the Examiner's characterization of this art field as unpredictable. The Examiner has a cited a handful of references reporting unique findings for a disparate group of proteins wherein mRNA expression did not correlate with protein expression. Applicants do not believe that these references are representative of what is believed by those skilled in the art.

Instead, teachings far more representative of the general understanding of those skilled in this art field can be found in references such as U.S. Patent 5,733,748, cited by the Examiner in the above Section. As acknowledged by the Examiner, this prior art reference teaches colon specific genes and proteins encoded thereby. As also acknowledged by the Examiner, this

reference teaches diagnosis of colon cancer by "detecting altered levels of CSG polypeptides in a biological sample, tissue, elevated levels of CSG polypeptides, wherein the assays are well known in the art, wherein the tissue can be biological fluids, cell samples diagnosing colon cancer comprising measuring levels of CSG polypeptides." Accordingly, this reference establishes that for colon specific genes those skilled in the art expect a correlation between polynucleotide and polypeptide levels.

MPEP § 2164.04 states:

> a specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sough to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph, unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

The instant specification provides detailed teachings of diagnostic methods for colon cancer at pages 6 through 8. Detailed assay techniques for detecting a CSG in accordance with claim 1 are set forth in the specification at pages 9 through 11. In addition, detectable elevated levels of CSGs of the present invention in colon cancer is demonstrated by the data presented in the specification at pages 17-22. Thus, the instant specification clearly teaches one of skill how to make and use

the instant claimed invention.

Further, art most relevant to the instant claimed invention is supportive of the fact that polynucleotide levels of CSGs are expected to correlate with polypeptide levels. Accordingly, there is no reasonable basis to question the teachings of the instant specification.

Thus, the instant specification and claims meet the enablement requirements of 35 U.S.C. § 112, first paragraph. Withdrawal of this rejection is therefore respectfully requested.

III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Communication of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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Polypeptide encoded by SEQ ID NO:1

AERLKTSLQKALEEELEQRPRLGGLQPGQDRWRGPAMERPLPMEQARYLEPGIPPEQPHQRTLEHSLPPSPRPLPRH
TSAREPSAFTLPPPRRSSSPEDPERDEEVLNHVLRDIELFMGKLEKAQAKTSRKKKFGKKNKDQGGLTQAQYIDCFQ
KIKYSFNLLGRLATWLKETSAPELVHILFKSLNFILARCPEAGLAAQVISPLLTPKAINLLQSCLSPPESNLWMGLG
PAWTTSRADWTGDEPLPYQPTFSDDWQLPEPSSQAPLGYQDPVSLRRGSHRLGSTSHFPQEKTHNHDPQPGDPNSRP
SSPKPAQPALKMQVLYEFEARNPRELTVVQGEKLEVLDHSKRWWLVKNEAGRSGYIPSNILEPLQPGTPGTQGQSPS
RVPMLRLSSRPEEVTDWLQAENFSTATVRTLGSLTGSQLLRIRPGELQMLCPQEAPRILSRLEAVRRMLGISP